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Special 510(k) Summary of Safety and Effectiveness: Line Extension to the Xia® Titanium Spinal System and Xia® Stainless Steel Spinal System

Proprietary Name:	Xia® Titanium Spinal System and Xia® Stainless Steel Spinal System
Common Name:	Spinal Fixation Appliances
Proposed Regulatory Class:	Class III Spinal Interlaminal Fixation Orthosis, 21 CFR 888.3050 Spinal Intervertebral Body Fixation Orthosis, 21 CFR 888.3060 Pedicle Screw Spinal System 21 CFR 888.3070(b)(1) and (b)(2)
Device Product Code:	NKB, MNH, MNI, KWP, KWQ
For Information contact:	Simona Voic Regulatory Affairs Project Manager 2 Pearl Court Allendale, NJ 07401 Telephone: (201) 760-8145 Fax: (201) 760-8345 Email: Simona.Voic@stryker.com
Date Summary Prepared:	June 29, 2006
Predicate Devices	Stryker Spine Xia® Titanium Spine System K060361, K013823, K002858, K022160.

JUL 27 2006

	Stryker Spine Xia® Stainless Steel Spine System K060361, K031090, K012870.
Description of Device Modification	This 510(k) is intended to introduce an extension to the existing Xia®Titanium Spinal System and Xia®Stainless Steel Spinal System that includes long arm bone screws and hooks.
Intended Use	The Xia® Spinal System is intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. The 6 mm diameter rods from the DIAPASON™ Spinal System and OPUS™ Spinal System are intended to be used with the other components of the Xia® Titanium Spinal System. The Titanium Multi-Axial Cross Connectors are intended to be used with the other components of the Xia® Titanium Spinal System.
Summary of the Technological Characteristics	Documentation is provided which demonstrates the new long arm bone screws and long arm hooks of the Stryker Spine Xia® Titanium Spinal System and Xia® Stainless Steel Spinal System to be substantially

equivalent to its predicate devices in terms of its material, design, and indications for use. Engineering analysis to demonstrate compliance with FDA's Guidance for Spinal System 510(k)'s May 3, 2004 was completed for the Stryker Spinal Xia® Titanium Spinal System and Xia® Stainless Steel Spinal System Long Arm Bone Screws and Long Arm Hooks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 20 2012

Stryker Spine
% Ms. Simona Voic
Regulatory Affairs Project Manager
2 Pearl Court
Allendale, New Jersey 07401

Re: K061854
Trade/Device Name: Xia® Titanium Spinal System & Xia® Stainless Steel Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWP, KWQ
Dated: June 29, 2006
Received: June 30, 2006

Dear Ms. Voic:

This letter corrects our substantially equivalent letter of July 27, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061854

Device Name: _ Line Extension to the Xia® Titanium Spinal System and Xia® Stainless Steel Spinal System

Indications for Use:

The Xia® Spinal System is intended for anterior/anterolateral and posterior, noncervical pedicle and non-pedicle fixation for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The 6 mm diameter rods from the DIAPASON™ Spinal System and OPUS™ Spinal System are intended to be used with the other components of the Xia® Titanium Spinal System. The Titanium Multi-Axial Cross Connectors are intended to be used with the other components of the Xia® Titanium Spinal System.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061854